



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

I-010697-P-0069

APR 19 2007

• U.S. Department of Interior
Fish and Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Request to review Effectiveness final study report (FLOR-01-EFF.3-27) and the Effectiveness technical section for AQUAFLO

Dear Dr. Erdahl:

Based on the information in your submission dated November 29, 2006, and amended on January 11, 2007, and the information contained in the Investigational New Animal Drug (INAD) file 010697, the Division of Therapeutic Drugs for Food Animals considers the Effectiveness technical section for AQUAFLO (florfenicol) Type A Medicated Article for the control of mortality in freshwater-reared salmonids due to furunculosis associated with *Aeromonas salmonicida*, when administered at a dose of 10 mg/kg of fish/day for 10 consecutive days to be complete.

We will make a final decision on whether we can approve your application after we have reviewed all of the data for all applicable technical sections submitted in support of an Administrative New Animal Drug Application (NADA), NADA, or supplemental NADA, and any other information available to us, as a whole, and determined whether the requirements for approval set forth in the Federal Food, Drug, and Cosmetic Act have been met.

If you submit correspondence relating to your submission to the investigational file, you should reference this letter by date and the principal submission(s) identifier found at the top of this letter. If you have any questions, please contact me at (301) 827-7571 or Dr. Donald Prater, Leader, Aquaculture Drugs Team, at (301) 827-7567.

Sincerely,

Joan C. Gotthardt, D.V.M.
Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure: Freedom of Information Summary (Effectiveness section)